



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference ES032PCT		FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEAA16)
International application No. PCT/CH 02/00349	International filing date (day/month/year) 26.06.2002	Priority date (day/month/year) 26.06.2002	
International Patent Classification (IPC) or both national classification and IPC A61B5/042			
Applicant ENDONSENSE S.A.R.L. et al.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.18 and Section 807 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 5 sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 21.01.2004		Date of completion of this report 05.08.2004	
Name and mailing address of the International preliminary examining authority:  European Patent Office D-80293 Munich Tel: +49 89 2399-0 Fax: 523658.epmu.d Fax: +49 89 2399-4465		Authorized Officer: Schoeffmann, H. Telephone No. +49 89 2399-2625 	

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/CH 02/00349**

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).
(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-4

because:

☒ the said international application, or the said claims Nos. 1-4 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer-readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 5

No: Claims

Inventive step (IS) Yes: Claims 5

No: Claims

Industrial applicability (IA) Yes: Claims 5

No: Claims

2. Citations and explanations

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/CH 02/00349**

I. Basis of the report

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

4-7 as originally filed
1-3, 3a filed with telefax on 23.07.2004

Claims, Numbers

1-5 filed with telefax on 23.07.2004

Drawings, Sheets

1/3-3/3 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

Section III:

1. For the assessment of the present claims 1-4 on the question whether they are industrially applicable, no unified criteria exist in the PCT. The IPEA therefore is not required to carry out an examination on these claims (Cf. Rule 67.1(iv) PCT).

The patentability may be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body.

The above claims pertain to a method of cardiac catheterisation which is considered surgical in its nature as it implies the insertion of a catheter into the human or animal body, be it by way of incision or by using natural body orifices. Thereby the entire method is rendered surgical. Methods of surgery might not be regarded as an invention susceptible of industrial application.

Section V:

1. Claim 5 relates to a cardiac catheterisation system comprising a catheter and a processor for detecting and analysing the position of the catheter within the heart. The catheter is provided with a dipole for position detection. A system of that kind is disclosed in US 6370 412 which is considered closest prior art.

Problems might occur in detecting the catheter position when its tip is inverted. This problem is overcome by additional use of a flow-sensor for detection of blood flow direction so that an inadvertent catheter inversion may be reliably transformed into GO, STOP and END commands given by the processor to the operator. As the distinguishing feature is not shown in any of the prior art documents cited in the ISR, claim 5 is considered to meet the requirements of Art.33 (2)-(4) PCT.

26-07-2004

CH0200349

Reply to Written Opinion of 28.06.04

PCT/CH2002/000349

ANNEX B - REPLACEMENT PAGES 1-3A OF THE DESCRIPTION
(replacement page 1 based on amended p. 1, line 1-14 in PCT/CH2002/000349)

1

CATHETERIZATION METHOD AND SYSTEM

5 FIELD OF INVENTION

The present invention relates to a method and system for cardiac catheterization for controlling the displacement of a catheter with respect to the heart of a patient and correcting any undesirable deviation of the catheter tip.

BACKGROUND OF INVENTION

10 Conventional catheterizations controlled by fluoroscopy are generally performed in hospitals, require complex X-ray equipment installed in a particular hospital facility such as a catheterization laboratory or radiology department and must be carried out by specially qualified physicians trained in catheterization procedures. Consequently, these conditions cannot be met in emergencies when the equipment and trained personnel required for catheterization are not readily available.

15 However, in many cases where there is an urgent need for catheterization, the rapid transfer of severely ill patients to a suitably equipped location can be quite problematic and may entail serious risks, even in the case of in-hospital interventions. The transfer of a patient to the next suitably equipped hospital usually takes some time and could affect the patient's chances of survival.

U.S. Pat. No. 6,370,412 relates to a method and apparatus for guiding ablative therapy of abnormal
20 biological electrical excitation by placing passive and active electrodes in or on the body of a patient and electrical energy is delivered to the active electrode(s) to determine the relative locations of the electrical source and the active electrode. It thus relates to a method of cardiac catheterization for guiding a catheter via signals resulting from the cardiac activity of the patient.

W0 99/45994 relates to a remote control catheterization system including a propelling device,
25 which controllably inserts a flexible elongate probe into the body of a patient. A control console, in communication with the propelling device, includes user controls, which are operated by a user of the system remote from the patient to control insertion of the probe into the body by the propelling device. The described remote control catheterization system comprises a fluoroscope for imaging the displacement of the catheter with respect to the heart of a patient.

30 U.S. Pat. No. 6,083,170 relates to a self-aligning catheter having a distal end preferably for insertion through physiological tissue. The catheter includes a sensor that generates signals indicative of a characteristic of the tissue in a vicinity of the probe, and an alignment mechanism, which deflects the distal end of the catheter in response to the signals delivered by the sensor. The signals may be indicative of an obstruction in the lumen in the tissue or of the direction of a clear channel in the lumen.

35 U.S. Pat. No. 5,492,131 relates to a servo-catheter guided by directional control inside a body passage by a servo-type system, which includes a sensor to transmit position, orientation or velocity information to a microprocessor that is typically programmed with an error detection algorithm, and a motion control system.

ANNEX B - REPLACEMENT PAGES 1-3A OF THE DESCRIPTION

(replacement page 2 based on p. 1, line 15 to p. 2, line 11 in PCT/CH2002/000349)

2

U.S. Pat. No. 5,391,199 relates to catheterization using fluoroscopy imaging to show the progress
5 of a catheter through a patient's body.

U.S. Pat. No. 6,246,898 relates to a method for carrying out a catheterization by using a 3-D
tracking and imaging system that may be configured as a catheter guidance system.

A system for externally locating a catheter described in U.S. Patents No. 4,173,228, No. 5,425,367
and No. 5,645,065 comprises an external probe for locating a catheter tip having an inductive coil for
10 delivering an induced signal in response to a rotating magnetic field generated by the external probe.

However, in the majority of situations requiring catheterization, the heart's structures are the main
targets of interest for intervention and they constitute moving targets with variable coordinates, which
can only be determined with a limited degree of accuracy.

Externally positioned 3-D sensors do not allow the intravascular position of the catheter to be
15 ascertained and some degree of control by fluoroscopy is nevertheless necessary.

SUMMARY OF THE INVENTION

An object of the present invention is to provide a compact, portable catheterization system suitable
for widespread use to rapidly perform catheterizations in different settings by various types of
medical personnel.

20 The present invention enables the advance of a catheter to be effectively monitored by using
signals delivered by a mobile sensor to detect any deviation preventing the advance of the catheter.
The drawbacks and limitations of various proposed imaging, tracking and mapping techniques
proposed are thereby effectively avoided.

The term catheter is generally applied here in its broadest possible sense in connection with the
25 present invention and is meant to include any elongated flexible member such as a cardiac catheter,
guide wire, pacemaker lead or the like guided along a blood vessel in accordance with this invention.

Signals delivered by the sensor arranged on the catheter according to the present invention
represent impulses associated with the cardiac activity and correspond to an internal cardiogram of a
patient, and have thus been called cardiac signals with reference to the invention.

30 The present invention now makes it possible to effectively guide a catheter along a blood vessel by
combining a sensor with an electronic unit to enable or interrupt the advance of the catheter.

Said monitoring signals delivered by the sensor are modified by an inversion of the position of the
catheter tip and enable any deviation preventing the advance of the catheter to be detected.

The catheter may be provided with any suitable sensor to deliver monitoring signals that are
35 modified by any deviation preventing the advance of the catheter. Such a modification of said signals
correspond to an inversion of the catheter tip and may be obtained by a corresponding reversal of the
direction of the flow of blood at the catheter tip.

ANNEX B - REPLACEMENT PAGES 1-3A OF THE DESCRIPTION

(replacement page 3 based on p. 2, line 19 to p. 3, line 13 in PCT/CH2002/000349)

3

A bipolar electrode may be used advantageously to obtain monitoring signals corresponding to a
5 reference voltage to enable the advance of the catheter or to a second voltage to interrupt its advance.

The method of cardiac catheterization according to the invention provides for monitoring the
advance of the catheter by providing the catheter with at least one sensor serving to detect any
inversion of the catheter tip, to deliver cardiac signals representing an internal cardiogram of the
patient and to thereby provide monitoring signals to enable or to interrupt the advance of the catheter
10 in order to return the catheter tip to a position enabling its further advance.

This method of catheterization moreover enables the position of the catheter tip in contact with the
wall of the heart cavity to be verified by creating impulses at the tip of the catheter and detecting the
appearance of corresponding induced signals on a surface cardiogram of the patient.

It moreover enables the entry of the catheter tip into the heart atrium of the patient to be readily
15 verified by detecting a significant increase in the amplitude of cardiac signals corresponding to atrial
impulses and appearing on said internal cardiogram.

In addition, the passage of the catheter tip from the atrium to the ventricle of the patient may be
readily verified by detecting a significant increase in the amplitude of the cardiac signals
corresponding to ventricular impulses and appearing on said internal cardiogram.

20 The present invention provides a cardiac catheterization system characterized by a catheter
provided with at least one sensor that comprises a bipolar electrode and a flow sensor and is adapted
to deliver cardiac signals that represent an internal cardiogram of a patient undergoing catheterization
and are modified by any deviation of the catheter tip preventing the advance of the catheter, a central
processor connected to said sensor via a first filter, a first analog-to-digital converter and a first signal
25 processor, said central processor further being connected to a device for obtaining a surface
cardiogram of the patient via a second filter, a second analog-to-digital converter and a second signal
processor, said central processor being adapted to deliver a GO signal, a STOP signal and an END
signal to respectively enable, interrupt or terminate the advance of the catheter.

Said catheterization system is advantageously provided with a mobile sensor comprising a bipolar
30 electrode adapted to deliver said cardiac signals and to generate impulses.

The invention may be carried out to meet various diagnostic and therapeutic functions with a
catheterization system comprising a catheter provided with a bipolar electrode and a flow sensor.

ANNEX B - REPLACEMENT PAGES 1-3A OF THE DESCRIPTION

(replacement page 3A same as p. 3, lines 14-35 in PCT/CH2002/000349)

3A

The invention may be illustrated by the embodiment described below by way of example with
5 reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows a bipolar electrode on the free end of a catheter.

Fig. 2 illustrates the path of the catheter in a patient undergoing a cardiac catheterization.

Fig. 2a is a schematic view of the heart region of the patient undergoing a cardiac catheterization

10 Fig. 2b to 2d indicate possible deviations of the catheter tip from the catheterization path.

Fig. 3 represents a block diagram of an electronic unit associated with the bipolar electrode.

Fig. 4 illustrates various signals relating to the catheterization.

DESCRIPTION OF PREFERRED EMBODIMENTS

The tip of the catheter C shown in Fig. 1 is provided with a sensor Sm in the form of a bipolar
15 electrode serving to deliver cardiac signals cs representing electrical impulses associated with the
cardiac activity of the patient and including a ventricular signal cv and an atrial signal ca
corresponding respectively to the ventricular complex and to the atrial wave of an internal cardiogram
of a patient undergoing catheterization. The bipolar electrode Sm also enables the emission of
electrical impulses in the heart of the patient.

20 Fig. 2 represents points 1 to 4 indicating various positions of the bipolar electrode Sm on the path
of the catheter C extending from the femoral vein to the vena cava inferior of a patient and points 5
and 6, 7 respectively indicating positions of the catheter tip in the right atrium and in the right
ventricle of the patient's heart. Fig. 2 and 2a further represent the points 2d, 3d and 5d indicating
possible deviations of the catheter tip from the required path 1 to 7.

25 A device SCG for measuring a surface-cardiogram, comprising stationary sensors in contact with

ANNEX A - NEW CLAIMS 1-5

(Replacement page 8)

8

Claims

- 5 1. A method of cardiac catheterization for controlling the displacement of a catheter tip with respect to the heart of a patient and correcting any undesirable deviation of the catheter tip, characterized by:
- (a) producing monitoring signals during the advance of the catheter along a blood vessel by providing the catheter (C) with at least one sensor (Sm) adapted to deliver cardiac signals that
10 represent an internal cardiogram of the patient and are modified by any deviation of the catheter tip preventing the advance of the catheter,
- (b) comparing said monitoring signals with a reference during the advance of the catheter,
- (c) enabling the advance of the catheter when said monitoring signals correspond to said
15 reference and interrupting the advance of the catheter when said monitoring signals deviate from said reference in order to return the catheter tip to a position enabling its advance.
2. The method according to claim 1, characterized by verifying the entry of the catheter tip into the heart atrium of the patient by detecting an increase in the amplitude of cardiac signals
corresponding to the atrial impulses appearing on said internal cardiogram of the patient.
3. The method according to claim 2 characterized by verifying the passage of the catheter tip
20 from the atrium to the ventricle of the patient by detecting a significant increase in the amplitude of the cardiac signals corresponding to ventricular impulses that appear on said internal cardiogram of the patient.
4. The method according to claim 3, characterized by verifying the contact of the catheter tip with the wall of the heart cavity by creating impulses at the tip of the catheter and detecting the appearance
25 of corresponding induced signals on a surface cardiogram of the patient.
5. A cardiac catheterization system characterized by:
- (a) a catheter (C) provided with at least one sensor (Sm) that comprises a bipolar electrode and a flow sensor and is adapted to deliver cardiac signals that represent an internal cardiogram of a patient undergoing catheterization and are modified by any deviation of the catheter tip preventing the
30 advance of the catheter,
- (b) a central processor (CP) connected to said sensor (Sm) via a first filter (F1), a first analog-to-digital converter (A/D1) and a first signal processor (SP1), said central processor (CP) further being connected to a device (SCG) for obtaining a surface cardiogram of the patient via a second filter (F2), a second analog-to-digital converter (A/D2) and a second signal processor (SP2), said central
35 processor (CP) being adapted to deliver a GO signal, a STOP signal and an END signal to respectively enable, interrupt or terminate the advance of the catheter.